DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 11, 2014

Ranfac Corporation
Mr. Christopher P. Whelan
Senior Vice President
30 Doherty Avenue
Avon, Massachusetts 02322

Re: K140991
Trade/Device Name: Ranfac Aspirating Needle with Adjustable Guide
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: September 2, 2014
Received: September 3, 2014

Dear Mr. Whelan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140991

Device Name
Ranfac Aspirating Needle with Adjustable Guide.

Indications for Use *(Describe)*
The Ranfac Aspiration Needle with Adjustable Guide is intended for use for aspiration of bone marrow or autologous blood using a standard piston syringe.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Ranfac

Precision instruments for specialized applications

SECTION 5

K140991
510(k) Summary

The contents of this 510(k) summary on the following pages have been provided in conformance with 21 CFR § 807.92 Content and format of a 510(k) summary.

510(k) Summary

Owner's Name and Address:	Ranfac Corp. 30 Doherty Avenue Avon, MA 02322-0635 FDA Registration Number 1211566
Official Contact Person:	Christopher P. Whelan Senior Vice President Telephone: 508-588-4400 extension: 106 Facsimile: 508-584-8588 e-mail: cwhelan@ranfac.com
Date Summary Prepared:	April 15, 2014
Device Trade Name:	**Ranfac Aspiration Needle with Adjustable Guide**
Common Name:	Needle, Aspiration and Injection, Disposable
Classification Name:	Gastroenterology-urology biopsy instrument (KNW) Subpart B Diagnostic Devices 21 CFR § 876.1075, Gastroenterology-urology biopsy instrument, Class II

RANFAC CORP. | PO BOX 635 | 30 DOHERTY AVE | AVON, MA 02322 | USA
Phone: 508-588-4400 | 800-272-6322 | Fax: 508-584-8588 | Email info@ranfac.com
www.ranfac.com
since 1888

Ranfac

Precision instruments for specialized applications

510(k) Summary

Predicate Device:

510(k) Number	Predicate Description	Manufactured By
K131157	Ranfac Bone Marrow Aspiration Needle	Ranfac Corp.
K121181	SwannShidi Bone Marrow Aspiration Needle	Alliance Partners, LLC

Background

The Ranfac Aspiration Needle with Adjustable Guide is a variation of the Ranfac Bone Marrow Aspiration Needle (K131157). The Ranfac Aspiration Needle with Adjustable Guide is intended for use for aspiration of bone marrow or autologous blood using a standard piston syringe. The Ranfac Aspiration Needle with Adjustable Guide works in a similar manner to the Ranfac Bone Marrow Aspiration Needle in that it enters the bone by the user applying pressure to the needle/stylet while twisting the handles. Once the needle enters the marrow cavity, the Stylet is removed and a Blunt Stylet is inserted and the needle is advanced to the desired location as set by the Adjustable Guide. Aspiration is performed by attaching a syringe to the Luer fitting of the needle and applying negative pressure. The needle can be partially withdrawn to continue to aspirate from different areas prior to complete withdrawal.

Device Description:

The Ranfac Aspiration Needle with Adjustable Guide consists of a stainless steel cannula, and two stainless steel stylets. All of the aforementioned have handles molded of ABS plastic. The cannula has an Adjustable Guide, also molded of ABS plastic that can be used as a depth guide.

RANFAC CORP. | PO BOX 635 | 30 DOHERTY AVE | AVON, MA 02322 | USA
Phone: 508-588-4400 | 800-272-6322 | Fax: 508-584-8588 | Email info@ranfac.com
www.ranfac.com
since 1888

Ranfac

Precision instruments for specialized applications

510(k) Summary

Intended Use:

The Ranfac Aspiration Needle with Adjustable Guide is intended for use for aspiration of bone marrow or autologous blood using a standard piston syringe.

Technological Characteristics:

The Ranfac Aspiration Needle with Adjustable Guide is similar in materials and design to the predicate devices. All devices are comprised of stainless steel cannula and stylets with mating plastic handles. All devices have luer fittings enabling the use of standard piston syringes.

Non-clinical Data: Standards

The Stainless Steel Cannula and Stylets, contact the patient in a limited use, and is in conformance with ISO 9626 First edition 1991-09-01, Amendment 1 2001-06-01 Stainless steel needle tubing for the manufacture of medical devices. FDA Standards Recognition Number 6-163.

The luer lock connection that is molded as part of the plastic handle is in conformance with ISO 594/1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements. FDA Standards Recognition Number 6-11.

The luer lock connection that is molded as part of the plastic handle is in conformance with ISO 594-2 Second edition 1998-09-01, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings. FDA Standards Recognition Number 6-129.

RANFAC CORP. | PO BOX 635 | 30 DOHERTY AVE | AVON, MA 02322 | USA
Phone: 508-588-4400 | 800-272-6322 | Fax: 508-584-8588 | Email info@ranfac.com
www.ranfac.com
since 1888

Ranfac

Precision instruments for specialized applications

The following standards apply to the sterilization of the finished device.

ISO 11135-1, Sterilization of health care products – Ethylene Oxide – Part1: Requirements for development, validation and routine control of a sterilization process for medical devices. FDA Recognition Number 14-331.

ISO 10993-7, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals. FDA Recognition Number 14-278.

AAMI/ANSI/ISO 14161:2009, Sterilization of health care products – Biological indicators – Guidance for the selection, use and interpretation of results. FDA Recognition Number 14-285

ISO 11607-1:2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems. FDA Recognition Number 14-355

Clinical Data:

Not applicable

Conclusion:

Based on the similarities in materials, design, principles of function, biocompatibility and sterilization between the Ranfac Aspiration Needle with Adjustable Guide, subject of this premarket notification and the predicate devices, the Ranfac Aspiration Needle with Adjustable Guide has been shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

RANFAC CORP. | PO BOX 635 | 30 DOHERTY AVE | AVON, MA 02322 | USA
Phone: 508-588-4400 | 800-272-6322 | Fax: 508-584-8588 | Email info@ranfac.com
www.ranfac.com
since 1888